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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/064,903	08/27/2002	Hans Bigalke	BIO001PCTCIP	7981
30008	7590	12/05/2003		
GUDRUN E. HUCKETT LONSSTR. 53 WUPPERTAL, 42289 GERMANY			EXAMINER ROBINSON, HOPE A	
			ART UNIT 1653	PAPER NUMBER

DATE MAILED: 12/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/064,903

Applicant(s)

BIGALKE ET AL.

Examiner

Hope A. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The Preliminary Amendment filed December 5, 2002 has been received and entered.

Priority

2. It is noted that the instant application claims domestic priority under 35 U.S.C. 120 and/or 121 as a continuation-in-part to application number 09/700,540, filed January 19, 2001 which is a 371 of PCT/EP9903272, filed May 12, 1999 and foreign application claimed to serial number 198 21 285 filed May 13, 1998. However, the instant application claims 1 and 6 will only be awarded priority back to January 19, 2001 as sufficient support was not found in the other two documents. For instance there is no disclosure of sequences as claimed in the instant application.

Specification

3. The specification is objected to because of the following informalities:
The specification is objected to because on pages 3, 5, 6 and 11 for example, the word "gonorrheae" is misspelled as "gonorrhoeae". In addition, the specification is objected to because there are sequences disclose without the corresponding sequence identifiers (SEQ ID NO:), see page 5 for example.

Correction is required.

Claim Objection

4. Claims 1 and 6 are objected to because the claims recite specific sequences without the corresponding sequence identifiers (SEQ ID NO).

Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 6 recite “a protein undergoing at least one reaction of binding”, the term “undergoing” renders the claims indefinite because it does not describe the function or role of the protein in the reaction. The claim is also indefinite because the word “gonorrheae” is misspelled as “gonorrhoeae” (the dependent claims are also included in this rejection).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103 (a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 (c) and potential 35 U.S.C. 102 (f) or (g) prior art under 35 U.S.C. 103 (a).

7. Claims 1-4, 6-8 and 10-11 are rejected under 35 U.S.C. 103(a) as unpatentable over Slater et al. (The Journal of Immunology, vol. 140, no. 3, pages 807-811, 1988) taken with Borodic (U.S. Patent No. 6,429,189, December 10, 1999).

Slater et al. disclose immunotoxins-toxins covalently conjugated to specific antibodies. Slater et al. also disclose the avid binding of IgE antibodies to FcR on mast cells and basophils as suggesting the possible use of an IgE immunotoxin in the treatment of malignant mastocytosis. Slater et al. further disclose that IgE-ricin A chain significantly reduced

cutaneous histamine content. According to Slater et al. neither a mixture of IgE and ricin A chain that were not conjugated nor the induction of cutaneous mast cell degranulation with anti-IgE affected cutaneous histamine levels, therefore, IgE-ricin A chain produced a prolonged depletion of cutaneous histamine levels. Additionally, Slater et al. disclose that immunotoxins of this type bind to surface antigens through the antigen-binding site on the Fab portion of the molecule (see page 140). Slater et al. does not teach the botulinum toxin. However, Borodic teach that clostridium botulinum either directly or indirectly influences the system which involves mast cells, histamine, serotonin in such a fashion to cause a blocked physiological response (i.e. alterations to mast cell secretion or degranulation), column 4. Borodic reports that mast cells pretreated with botulinum toxin causes inhibition of secretion and that a mutant or derivative strain has produced a non-neurotoxin protein (botulinum C2), which demonstrates a selective interaction with mast cell (see columns 5-6). In addition it is well known in the prior art that botulinum toxin and tetanus toxin are produced by closely related microorganisms and possess some structural and functional similarities.

Accordingly, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention as a whole because Slater et al. teach a conjugate (hybrid, see page 6 of the specification) that exhibits affinity to mast cells and basophils. Furthermore, Slater et al. demonstrates that the IgE coupled with ricin produced the effect of lowering histamine levels. In-so-far-as Slater et al. does not specifically teach the tetanus or clostridium botulinum, it is well known in the prior art that botulinum toxin and tetanus toxin are produced by closely related micro-organisms and possess some structural and functional similarities and Borodic disclose botulinum toxin and provides motivation to use this toxin to produce and allergic response. The combined teachings of the references disclose a hybrid protein that binds to mastocytes and basophils and a protease (toxin) that inhibits the secretion process and makes the strong association between botulinum toxin and mast cell degranulation. Therefore, one of ordinary

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skill in the art would be motivated to modify the teachings of Slater et al. by adding the toxin of Borodic as an effective therapy of allergic reactions with a reasonable expectation of success because Slater et al. demonstrated that a similar toxin was effective in reducing histamine levels. Thus, the claimed invention as a whole was obvious to make and use.

Conclusion

8. No claims are allowable.


Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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Hope A. Robinson, MS 
Patent Examiner